

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES***

Applicant: Philippe MSIKA
Title: COSMETIC METHOD FOR PREVENTING
AND/OR TREATING SKIN STRETCHMARKS,
AND USE IN DERMATOLOGY
Appl. No.: 10/808,701
Filing Date: 3/25/2004
Examiner: Gina C. YU
Art Unit: 1611
Confirmation No.: 6071

REPLY BRIEF

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Sir:

Under the provisions of 37 C.F.R. § 41.41, this Reply Brief is being filed in response to the Examiner's Answer mailed June 10, 2010 in the above-identified application. This Reply is timely filed. No fee is due; however, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 19-0741.

ARGUMENT IN REPLY TO EXAMINER'S ANSWER

The Examiner's Answer is deficient for the reasons presented below.

A reasonable level of predictability is required for establishing a prima facie case of obviousness. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.).

The Examiner's Answer stated (page 13, lines 3-7 from bottom):

[A] reasonable person of ordinary skill in the art would have understood that the purpose of the journal article [Frei] was to teach the effect of soya peptide on a dermal and skin equivalent model so that others in the field would learn and envisage potential uses of the active ingredient and further develop it into useful articles.

This passage indicates reliance on the art of record as offering an invitation to do research (a) to confirm Frei's speculation about the action of soya peptides, (b) to confirm Rapaport's speculation that alpha hydroxy acids reduce stretchmarks by promoting skin rigidity and elasticity, and (c) to confirm that any compound that promotes skin rigidity and elasticity would reduce stretchmarks.

This is not a sound basis for establishing obviousness, because this fails to establish a reasonable expectation of success. Thus, the rejection should be reversed.

Further, Applicants pointed to (1) statements of uncertainty and doubt in Frei and (2) supporting Declaration testimony by a co-inventor regarding Frei and Rapaport. These

further establish that no reasonable expectation of success existed that a soya peptide could successfully treat stretchmarks.

The Examiner's Answer did not address the speculative nature of the disclosures in Frei and Rapaport that formed the basis of the obviousness rejection.

I. THE EXAMINER'S ANSWER FAILS TO ADDRESS FREI'S STATEMENTS OF UNCERTAINTY

The Examiner's Answer does not address Frei's clear statements of uncertainty regarding the action of soya peptides in the model used in Frei.

The following passage from Frei reveals why Frei's statements relied on by the examiner would be considered speculative by a person of ordinary skill in the art (arrows indicate relevant sentences):

After 25 days of culture, the reconstituted epidermis showed some signs of ageing such as a reduction in the number of keratinocyte layers and a flatness of the basal membrane. However, after 15 days of soya peptide treatment, SEs present an epidermis which is morphologically closer to normal human skin than to control SEs. Keratinocyte renewal and differentiation has been strengthened by the application of soya peptide which might also delay the *in vitro* process of ageing.

On a study model which reproduces the environment in which dermal fibroblasts and keratinocytes develop *in vivo*, the significant stimulating effect of a soya peptide on extracellular matrix component synthesis and its action on epidermal differentiation have been shown clearly. This peptide is able to stimulate regeneration of metabolic activity, which may help the skin to look younger.

Frei, p. 171, 3d-4th paras. In the context of the quoted passages, the words "might" and "may" are speculative. Frei states "the application of soya peptide ... **might** ... delay the *in vitro* process of aging," Frei, p. 171, 3d full para., last sentence (emphasis added) and "[t]his peptide is able to stimulate regeneration of metabolic activity, which **may** help the skin to look younger," Frei, p. 171, 4th full para., last sentence (emphasis added).

The words "might" and "may" are defined as an expressions of possibility, i.e., these words are inherently speculative (see dictionary.com):

might¹  [mahyt]  [Show IPA](#)



–auxiliary verb

1. pt. of *may*¹.

2. (used to express possibility): *They might be at the station.*

3. (used to express advisability): *You might at least thank me.*

4. (used in polite requests for permission): *Might I speak to you for a moment?*

may¹  [mey]  [Show IPA](#)

–auxiliary verb, *present singular 1st person may, 2nd may or (Archaic) mayest or mayst, 3rd may; present plural may;*

past might.

1. (used to express possibility): *It may rain.*

2. (used to express opportunity or permission): *You may enter.*

3. (used to express contingency, esp. in clauses indicating condition, concession, purpose, result, etc.): *I may be wrong but I think you would be wise to go. Times may change but human nature stays the same.*

4. (used to express wish or prayer): *May you live to an old age.*

5. *Archaic* . (used to express ability or power.)

To confirm the speculative nature of Frei’s assertions about the action of soya peptide, Frei plainly states “no conclusion could also be drawn concerning the way the soya peptide acts in this SE model” (see final sentence of the following passage):

Although a significant protective effect of the epidermis in this SE model has been demonstrated in another study [25], because of its low molecular weight, the tested soya peptide may cross the epidermal barrier (*ex vivo* percutaneous absorption study and *in vivo* study, N. Abdul Malak and E. Perrier, unpublished paper). In addition no conclusion could also be drawn concerning the way the soya peptide acts in this SE model.

Frei, p. 171, last sentence first full paragraph. This is a clear and specific statement leaving no room for a reasonable expectation of success.

The Examiner’s Answer should have addressed this point but did not.

The examiner relied entirely on this speculative disclosure in Frei to connect Frei (soya protein for skin firmness and elasticity) to Rapaport (glycolic acids for treating stretchmarks). The examiner did not allege any structural similarity between Rapaport’s compounds and Frei’s compounds or those of the present invention as claimed. Indeed, no such structural similarity exists; the Office conceded that Rapaport fails to teach a soya peptide. Examiner’s Answer, page 5, line 7.

Thus, the Board should reverse the obviousness rejection for failing to establish a prima facie case of obviousness.

II. THE EXAMINER'S ANSWER FAILS TO PROPERLY CONSIDER THE DECLARATION TESTIMONY REGARDING FREI AND RAPAPORT

The Examiner's Answer also failed to adequately consider testimony in the Rule 132 Declaration (filed November 14, 2008, and included in the Evidence Appendix of the Appeal Brief) providing strong evidence of nonobviousness over the art of record.

The Declaration provides objective testimony based on Frei's own statements expressing doubt. Regarding Frei, the Declaration states:

6. Frei provides no basis to infer that soya peptide increases skin firmness, elasticity, and tone. Frei does not directly state that soya peptide increases skin firmness, elasticity, and tone. Frei describes a skin equivalent (SE) model, but Frei lacks any objective measurement of skin firmness, elasticity, and tone. Frei states "the application of soya peptide ... might ... delay the in vitro process of aging." Frei, p. 171, 3d full para., last sentence (emphasis added). Frei further states "[t]his peptide is able to stimulate regeneration of metabolic activity, which may help the skin to look younger," Frei, p. 171, 4th full para., last sentence (emphasis added). The use of "might" and "may" in the sentences quoted above indicates that the authors were uncertain of these assertions.

7. Frei is equivocal about soya peptide's effect on ageing and recognizes that no definite conclusion is possible. Frei states "no conclusion could be drawn concerning the way the soya peptide acts in this SE model." Frei, p. 171, first full paragraph, final sentence. In my opinion, a person of ordinary skill in the art reading Frei would not conclude that soya peptide increases skin firmness, elasticity, and tone.

The Examiner's Answer again erred in failing to recognize the Declaration as record evidence (Examiner's Answer, sentence bridging pages 10-11). Office personnel should consider all rebuttal arguments and evidence presented by applicants, and it is legal error not

to consider evidence presented. M.P.E.P. § 2145, citing *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) and *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996).

The Office must make factual findings supported by substantial evidence. In particular, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. ___, 82 U.S.P.Q.2d 1385, 1391 (2007).

Here, the Office has not met its burden to clearly articulate, in view of the Declaration testimony, why a person of ordinary skill in the art would have a “reasonable expectation of success” in combining Rapaport with Frei, in view of Frei’s expressions of uncertainty and the Declaration evidence.

Regarding Rapaport, the Examiner’s Answer does not allege that Rapaport provides evidence of a causal connection between stretchmarks and the action of alpha hydroxy acids. Instead, the Examiner’s Answer states (emphasis added; Examiner’s Answer, page 12, lines 5-9 from bottom):

The prior art has provided sufficient teaching for a skilled artisan to reasonably conclude that 1) alpha hydroxy acids are effective in treating stretchmark reduction and 2) preservation of collagen, production of interfibrillary material and promoting rigidity and elasticity were highly relevant in treating stretchmarks.

The examiner thus concedes that no causal connection is established between the presumed action of alpha hydroxy acids and treating stretchmarks.

Further, the Declaration states:

5. In my opinion, a person of ordinary skill in the art would not conclude from Rapaport that stretchmarks are treated by promoting the rigidity and elasticity of the skin. Rapaport speculates that alpha hydroxy acids reduce stretch

marks by (i) eliciting a hyperplastic response in the epidermis and dermis that counters the breakdown of collagen, or (ii) by stimulating the production of interfibrillary material such as glycosaminoglycans which promotes both rigidity and elasticity to the skin. See Rapaport column 4, lines 31-38. Rapaport contains no test data supporting these assertions. These proposed mechanisms in Rapaport for enhancing skin elasticity and rigidity are unsupported. Consequently, a person of ordinary skill in the art would consider these mechanisms to be speculative and unproven.

Consequently, the Office erred in characterizing Rapaport as establishing that stretchmarks are treated by promoting the rigidity and elasticity of the skin. As noted above, the examiner appears to recognize that Rapaport falls short of establishing such a connection. Instead, the examiner merely asserted “high relevance” between rigidity and elasticity and treating stretchmarks. Thus, the examiner erroneously relied on Rapaport’s speculation as basis for asserting obviousness.

Regarding claim 7, the Examiner’s Answer relied on an erroneous factual finding to support the rejection of claim 7 (“soya peptide is between about 0.1% and about 10% by weight”) based on Andary’s disclosure of 1% soya peptide in an anti-aging cream.

The Examiner’s Answer states that “both Andary and the present invention are directed to topical compositions which utilize soya peptide and its efficacy in improving aged skin condition” (Examiner’s Answer, page 14, lines 14-16.

This statement is plainly erroneous, because the present claims refer exclusively to treating “stretchmarks”. The record contains no basis to equate treating stretchmarks with anti-aging. Instead, the record contains Declaration testimony serving as evidence that these cannot be equated.

The examiner erred in failing to consider the Declaration testimony on this issue, specifically points 8 and 13 of the Declaration:

8. A person of ordinary skill in the art reading Frei and Rapaport would not conclude that a soya peptide would be effective for treating stretchmarks. Frei states, “In this model, the soya peptide increased the thickness of the epidermis.” See Abstract. While that effect may support anti-ageing properties, a person of ordinary skill in the art would not recognize effectiveness for treating stretchmarks.

...

13. A person of ordinary skill in the art would not conclude that a formulation that is effective for treating the effects of ageing in skin would also be effective in treating stretchmarks (striae distensae).

The above Declaration testimony directly refutes any attempt to relate skin aging to the treating of stretchmarks.

Consequently, the examiner’s apparent finding – that treating stretchmarks is identical with or somehow correlates to anti-aging for the purposes of establishing effective doses – constitutes reversible error.

CONCLUSION

For the reasons presented herein and in the Appeal Brief, the examiner committed reversible error in finally rejecting claims 1-24. Accordingly, the final rejection of claims 1-24 should be reversed.

Applicants respectfully submit that all claims on appeal are allowable. Applicants request reversal of the Examiner’s rejection of claims 12, 18-24, 26-32, and 34-44.

Under the provisions of 37 C.F.R. § 41.37, this Appeal Brief is being filed together with a credit card payment form in the amount of \$540.00 covering the 37 C.F.R. 41.20(b)(2) appeal fee.

If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 19-0741.

Respectfully submitted,

Date: 9-Aug-2010

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